

MONTANA BOARD OF PHARMACY
P O BOX 200513
HELENA, MT 59620-0513
Phone 406/841-2356 Fax 406/841-2305

HOME INFUSION PHARMACY COMPLIANCE REPORT

Pharmacy Name

License Number

City

Zip Code

Phone Number

Fax Number

E-Mail Address

Pharmacist-in-Charge

PIC License Number

Date of Report

Purpose of Report

Complaint ☐ Routine ☐ Follow-up ☐ Other _____

Pharmacy Staff

(Include R.Ph., Technician, Technician-in-training, Intern)

<u>Title</u>	<u>Name</u>	<u>License Number</u>	<u>On duty</u>
_____	_____	_____	<input type="checkbox"/> Yes <input type="checkbox"/> No
_____	_____	_____	<input type="checkbox"/> Yes <input type="checkbox"/> No
_____	_____	_____	<input type="checkbox"/> Yes <input type="checkbox"/> No
_____	_____	_____	<input type="checkbox"/> Yes <input type="checkbox"/> No
_____	_____	_____	<input type="checkbox"/> Yes <input type="checkbox"/> No
_____	_____	_____	<input type="checkbox"/> Yes <input type="checkbox"/> No
_____	_____	_____	<input type="checkbox"/> Yes <input type="checkbox"/> No
_____	_____	_____	<input type="checkbox"/> Yes <input type="checkbox"/> No
_____	_____	_____	<input type="checkbox"/> Yes <input type="checkbox"/> No
_____	_____	_____	<input type="checkbox"/> Yes <input type="checkbox"/> No

PHARMACY FACILITY

- | | | |
|---|---------------|--|
| 1. Is the pharmacy orderly and clean? | 24.174.819(1) | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 2. Are required current licenses posted in a conspicuous place? | 37-7-321(1) | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 3. Is there adequate space & suitable equipment? | 16.32.713(1) | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 4. Is the pharmacy secure? | 24.174.814 | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 5. Is there adequate space for all pharmacy operations and storage of drugs at a satisfactory location provided with proper lighting, ventilation & temperature controls? | 16.32.713(1) | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 6. Are controlled substances maintained with proper security? | 24.174.810(3) | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 7. Are schedule II pharmaceuticals properly stored? | 24.174.810(3) | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 8. Are pharmaceuticals stored at proper temperatures? | 24.174.810(3) | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 9. Does the electronic data system meet all requirements? | 24.174.817 | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 10. Does the system maintain the confidentiality and accuracy of patient and prescription information? | 24.174.818 | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 11. Does the pharmacy have current references? | 24.174.810 | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 12. Is the staff identified? | _____ | <input type="checkbox"/> Yes <input type="checkbox"/> No |

PHARMACEUTICAL DELIVERY TO PATIENT

- | | | |
|--|------------------------------|--|
| 1. Are contracts in place for the provision of services? (i.e. In Home or Institutional) | 16.32.702 | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 2. Are the administrator's duties defined in policy? | 16.32.703 | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 3. Are policies and procedures available (and followed)?
Manual last revised _____ | 16.32.703(b)
16.32.712(2) | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 4. Is there a system to disseminate clinical information to parties providing services to patients? | 16.32.705(1a) | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 5. How is medication use monitored? | 16.32.705(2a) | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 6. Are medication profiles maintained? | 16.32.705(2b) | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 7. Is there a system to monitor drug therapy? | 16.32.705(2b) | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 8. Are parenterals properly labeled? | 16.32.716(1) | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 9. Does the care plan identify skilled nursing services to be provided? | 16.32.705(3a) | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 10. Are clinical notes signed and incorporated into the chart? | 16.32.705(3b) | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 11. Is there a policy providing for notifying all parties of significant changes in patient condition? | 16.32.705(3d) | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 12. Is there a policy to identify who will start the first-time sterile product? | 16.32.705(4) | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 13. Is there documentation of education and counseling provided to the patient and family? | 16.32.706(1a) | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 14. Is there a care plan developed by HIP & contracted party providing services? | 16.32.70707(3) | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 15. Does the home care record include required information? | 16.32.707(1) | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 16. How are allergies and adverse drug reactions documented? | 16.32.707(1c) | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 17. Have patient rights & responsibilities been given to each patient and documented? | 16.32.707(1e) | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 18. Is there a QA program developed by HIP & contracted services to evaluate patient services? | 16.32.708(1) | <input type="checkbox"/> Yes <input type="checkbox"/> No |

19. Are antineoplastic drugs prepared/dispensed?		<input type="checkbox"/> Yes <input type="checkbox"/> No
20. If so, is their preparation compliant with rules?	16.32.717(1)	<input type="checkbox"/> Yes <input type="checkbox"/> No
21. Is the disposal of antineoplastic, infectious and hazardous waste in compliance with the Infectious Waste Management Act ?	16.32.718(1)	<input type="checkbox"/> Yes <input type="checkbox"/> No
22. Is there a policy in place for after hours service and/or consultation?	16.32.715(2d)	<input type="checkbox"/> Yes <input type="checkbox"/> No
23. Is there a procedure in place for patient counseling?	24.174.903(1)	<input type="checkbox"/> Yes <input type="checkbox"/> No
24. Are outdated pharmaceuticals removed from stock?	24.174.2301(1b)	<input type="checkbox"/> Yes <input type="checkbox"/> No
25. Are records of dispensing maintained for two years?	24.174.512	<input type="checkbox"/> Yes <input type="checkbox"/> No

RECORD KEEPING

1. Is the pharmacy registered with the D.E.A.?	21CFR1301	<input type="checkbox"/> Yes <input type="checkbox"/> No
2. Is the pharmacy Montana D.D. registration current?	24.174.1401(2)	<input type="checkbox"/> Yes <input type="checkbox"/> No
3. Is the D.E.A. Biennial Inventory current & available?	21CFR1304.11	<input type="checkbox"/> Yes <input type="checkbox"/> No
4. Is D.E.A. form 222 properly executed?	21CFR1305.06	<input type="checkbox"/> Yes <input type="checkbox"/> No
5. Are necessary Power of Attorney forms in place?	21CFR1305.07	<input type="checkbox"/> Yes <input type="checkbox"/> No
6. Are Schedule II records filed separately from other records?	21CFR1304.04	<input type="checkbox"/> Yes <input type="checkbox"/> No
7. Are controlled substance invoices filed properly?	21CFR1303.04	<input type="checkbox"/> Yes <input type="checkbox"/> No
8. Are controlled substance prescriptions filed properly?	21CFR1304.04	<input type="checkbox"/> Yes <input type="checkbox"/> No
9. Are controlled substance records maintained for 2 years?	21CFR1304.04	<input type="checkbox"/> Yes <input type="checkbox"/> No
10. Does pharmacy maintain perpetual inventory on C-II drugs?	_____	<input type="checkbox"/> Yes <input type="checkbox"/> No
11. Is the perpetual inventory reconciled on a regular schedule?	_____	<input type="checkbox"/> Yes <input type="checkbox"/> No
12. Have there been shortages or losses of CS in the past year?	_____	<input type="checkbox"/> Yes <input type="checkbox"/> No
13. If so, was the loss reported to DEA, Board of Pharmacy & local law enforcement?	CSAsection301	<input type="checkbox"/> Yes <input type="checkbox"/> No
14. Is the Certification of Pharmacist In Charge in place?	24.174.801	<input type="checkbox"/> Yes <input type="checkbox"/> No
15. Is the Pharmacist In Charge Agreement in Place? (Non-Pharmacist owner)	24.174.801	<input type="checkbox"/> Yes <input type="checkbox"/> No
16. Is the current Dept of Health & Human Services Survey available?	_____	<input type="checkbox"/> Yes <input type="checkbox"/> No

PHARMACY TECHNICIANS

1. Are support personnel properly registered?	24.174.701	<input type="checkbox"/> Yes <input type="checkbox"/> No
2. Are technicians and auxiliary personnel properly identified?	24.174.703(4)	<input type="checkbox"/> Yes <input type="checkbox"/> No
3. Is the current "Technician Utilization Certificate" posted?	24.174.712	<input type="checkbox"/> Yes <input type="checkbox"/> No
4. Is the utilization plan accessible and being used?	24.174.712	<input type="checkbox"/> Yes <input type="checkbox"/> No
5. Do the contents of the training course meet the requirements?	24.174.713	<input type="checkbox"/> Yes <input type="checkbox"/> No
6. Are the training documents available for inspection?	24.174.714	<input type="checkbox"/> Yes <input type="checkbox"/> No
7. Do the Technicians and support personnel understand their responsibilities and limitations?	24.174.705	<input type="checkbox"/> Yes <input type="checkbox"/> No
8. Is the standard ratio being observed?	24.174.711	<input type="checkbox"/> Yes <input type="checkbox"/> No
9. Has an application for increased ratio been requested?	24.174.711(4)	<input type="checkbox"/> Yes <input type="checkbox"/> No
10. If so, are the required documents in place?	24.174.711(4)	<input type="checkbox"/> Yes <input type="checkbox"/> No

PHARMACY INTERNS

1. Is the intern registered with the Board?	24.174.602	<input type="checkbox"/> Yes <input type="checkbox"/> No
2. Are all the requirements of Internship being met?	24.174.602	<input type="checkbox"/> Yes <input type="checkbox"/> No
3. Are the preceptor requirements being met?	24.174.604	<input type="checkbox"/> Yes <input type="checkbox"/> No
4. Are the required forms and reports in place?	24.174.612	<input type="checkbox"/> Yes <input type="checkbox"/> No

ADMINISTRATION OF VACCINES

- | | | |
|---|------------|--|
| 1. Has the RPh completed an accredited training course? | 24.174.503 | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 2. Does the RPh have a current C.P.R. certificate? | 24.174.503 | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 3. Are vaccines administered via established protocol? | 24.174.503 | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 4. Is there a current copy of the required C.D.C reference? | 24.174.503 | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 5. Are the required policies and procedures in place? | 24.174.503 | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 6. Are the required records maintained? | 24.174.503 | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 7. Is there proper endorsement on the pharmacy license? | 24.174.503 | <input type="checkbox"/> Yes <input type="checkbox"/> No |

COLLABORATIVE PRACTICE

- | | | |
|--|---------------|--|
| 1. Has the RPh provided an executed copy of the agreement to the board ? | 24.174.524(1) | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| 2. Does the agreement include all requirements? | 24.174.524(2) | <input type="checkbox"/> Yes <input type="checkbox"/> No |

If there are any violations noted on this report the pharmacist-In-Charge must respond in writing to the Board of Pharmacy office regarding all corrective action taken by the pharmacy for all Violations. If a response is not received in the specified time frame the compliance specialist will file a complaint with the Board of Pharmacy for possible disciplinary action during a regularly scheduled screening panel meeting. You will be notified in writing of the scheduled meeting date and violations. If a response is not received in the specified time frame the compliance specialist will be required to respond to the licensing violations.

Compliance Specialist's recommendations:

Actions required by this report:

Date required action must be completed: _____

Compliance Specialist

Date

I acknowledge that the noted violations have been explained to me and I have received a copy of this report.

Pharmacist-in-Charge or Pharmacist-on-duty

Date